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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Shipman

Application No.: 09/786,105

Filed: 26 February 2001

Title: Method and kit for the characterization of antibiotic-resistance mutations in mycobacterium tuberculosis

Attorney Docket No.: VGEN.P-055

Group Art Unit: 1637

Examiner: S. Chunduru

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Assistant Commissioner for Patents
Washington, D.C. 20231RESPONSE UNDER 37-CFR § 1.111

This is in response to the Official Action mailed August 14, 2002 for the above-captioned application. Reconsideration of the application in view of the remarks herein is respectfully requested.

The Examiner has maintained the restriction requirement. While Applicants will not further contest the restriction requirement at this juncture, they wish to point out that the Examiner's contention concerning the relevance of the Kapur reference is in error. The Examiner may not rely on the classification of a reference as a category X reference to support a *per se* conclusion that the reference is in fact anticipatory under any circumstances. Where a claim, such as present claim 1, has been amended and found to be both novel and inventive over this same reference, the gratuitous statement that claim 1, a claim that is not under examination, is anticipated is unjustified and improper. Applicants therefore challenge this statement, and request that the Examiner either (1) withdraw the restriction requirement so that all claims are at issue, in which case he may make the rejection with supporting explanation and reasoning if he deems it warranted, or (2) expressly withdraw the statement concerning claim 1.

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The Examiner objected to the specification, stating that Seq ID Nos. 1 and 2 are identical or duplicates of Seq ID Nos. 3 and 4. This is correct if one looks only at the nucleic acid sequences, which is what one is required to do in the context of the sequence rules. However, Seq. ID Nos. 1 and 2 are used to refer to amplification primers, while Seq. ID Nos. 3 and 4 are used to refer to sequencing primers. The latter are generally labeled, while amplification primers generally are not. The different sets of sequence labels are used to improve clarity as to which actual molecule, as opposed to the artificial definitions required by the sequencing rules, is being referred to. The Examiner has not stated why this is objectionable.

The Examiner rejected claim 14 under 35 USC § 112, second paragraph, as indefinite, asserting that it is unclear from the phrase "at least one combination of primer pairs" whether the claim requires a primer pair or 2 primer pairs. Applicants respectfully submit that the Examiner may not pluck one phrase out of a claim and determine that this phrase in the abstract may be indefinite. Rather, the Examiner must look at the claim as a whole. Here, if this is done, there is no possibility of ambiguity, because the "combinations of primer pairs" are expressly listed in the paragraphs identified by letters (a) through (j). The claims require that at least one of the identified sets of primer pairs be present. It is incumbent on the Examiner to establish that one having ordinary skill in the art would not have been able to determine the scope of protection defined by the claim when read in light of the specification. *In re Cordova*, 10 USPQ2d 1949, 1952 (POBAI 1989). In this case, the Examiner has not explained how this could be unclear to a person of skill in the art. Thus, he has failed to establish a basis for the rejection as required by law. The rejection should therefore be withdrawn.

The Examiner also stated that claim 14 is "indefinite and incomplete for being dependent on non-elected subject matter." To the extent this is understood, it appears that the Examiner is suggesting that Applicants must limit the claim to the elected species. However, Applicants know of no law which supports such a rejection, and thus are unsure of what the rejection may actually mean. Furthermore, to the extent it is ever proper to make a species election requirement in a 371 application, a point Applicants do not concede and which the Examiner has not established, it would still fall within the requirements of the related rules, which allow presentation of a generic claim encompassing the elected and non-elected species. The fact that the claim also encompasses other species is merely reflective of the

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inappropriateness of the species election in the first place, and was pointed out in the response to the restriction requirement. Thus, this ground for rejection either needs to be explained, in a non-final action, or withdrawn.

On the merits, the Examiner rejected claim 14 as anticipated by WO95/33851. The Examiner concedes that this rejection is based on the erroneous and unsupported interpretation of the claim where any two primers from the primers listed in a combination can be selected. Inasmuch as this is plainly not what the claim says, this rejection is in error and should be withdrawn.

The Examiner also rejected claim 14 under 35 USC § 103 as obvious over the combination of WO95/33851 in view of US Patent No. 5,851,763 and US Patent No. 5,985,569. Essentially the Examiner argues that WO95/22851 teaches the primer of sequence 1/3 and that one could derive the sequence of primer 2/4 from the complete sequence of the *rpoB* gene, as taught by the '763 patent, using the techniques of the '569 patents. In support of this, the Examiner cites *In re Deuel*, 34 USPQ 2d 1210 (Fed. Cir. 1995) and makes the argument that all primers derived from a sequence are equal and obvious. Neither of these arguments has merit.

First of all, applying the rule of law as stated in *Deuel* to the present case, evidence of the existence of general techniques for the identification of primers is irrelevant to the question of whether specific primers would have been obvious. Thus, the citation to Page 9 of WO95/33851 (which Applicants assume to be what the Examiner was referring to on Page 6 of the office action) and the '569 patent which describe general techniques, are of little relevance. The claims of this application relate to **specific combinations of primers**, and it is the patentability of these **combinations of primers**, not primers for the target gene (*rpoB* in the case of the elected species) generally, which must be considered. Nothing in the art, nor in the Examiner's arguments, points to these specific primer combinations.

Applicants further note that the Examiner has included his own argument as part of the asserted quotation from the Federal Circuit. Nothing in the *Deuel* case supports the contention that the claimed primers are structural homologs of anything taught in the art. The Examiner has not shown why a person skilled in the art would have been motivated to select the particular primers set forth in the claims out the millions of possible primer sequences that could

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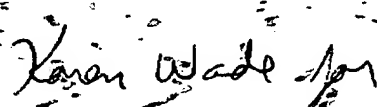
be selected. Absent such a showing, the Examiner has failed to make out a *prima facie* case of obviousness.

It should also be noted that it is technically inaccurate to assume that any and all primers work for amplification and sequencing with equal efficiency. For example, as shown in US Patent No. 6,228,577, a copy of which is attached, shifts of only a few bases in the position of a sequencing primer can make substantial differences in the quality of the sequencing results obtainable. Different primers work better than others, and different primer combinations work better than others. The primer sets recited in claim 14 were selected to work well with the other primers in the identified combination. Thus, the Examiner must base a rejection of a specific primer sequence on something more than a complete sequence and an invitation to experiment. The Examiner has not provided that "something more" here. The rejection should therefore be withdrawn.

Finally, Applicants note that the Examiner stated that a claim "which utilizes closed language that require the inclusion of primers 1-4 would overcome this rejection." Applicants point out that in the context of the elected species, the claims do require primers of sequences 1-4, although not all species within the genus require these particular primers. Since the Examiner has not addressed the other species, it is not clear why a narrowing to this scope would be required by the art. On the other hand, this statement is an admission that the elected species, when the claims are properly interpreted, is patentable over the art. The Examiner is therefore required to move on and consider the generic claims and the other species as a whole.

In view of the foregoing remarks, Applicants submit that the application is in form for allowance. Favorable reconsideration is urged.

Respectfully submitted,


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